

REMARKS

Surrender of original patent

The original Letters Patent is surrendered herewith.

Oath

Enclosed herewith are executed oaths by the inventors dated June 16, 2003, and June 17, 2003. Supplemental oaths are being sent to the inventors for execution and will be filed as soon as possible.

Status of claims

1-36 and 38-47 are pending.

Current amendments to the claims

Claim 35 has been amended to provide that the chambers are sterile and adjacent each other. This is clearly disclosed in figure 2. Claim 35 has also been amended to recite means for sterile transfer of a fluid to or from a chamber, which is language permitted by 35 USC 112, sixth paragraph, and reads on access ports 13 and 15 and their equivalents.

Claim 38 has been amended to recite a locking element that selectively holds the container in a predetermined orientation. This generic recitation is disclosed in the specification by the preferred locking plate 36.

Claims 40 and 42 have been amended to be consistent with claim 38 by reciting the locking plate specifically.

Claim 43 has been amended to recite the location of the bridge as at the top portions of the chambers and an access port also near the top of at least one of the chambers. This language is clearly disclosed, for example, in figure 2.

Amendments to the claims on February 28, 2003

Claim 32 was amended to provide that the first and second chambers are adjacent each other. This feature is disclosed in figure 2. Claim 32 was also amended to recite that the bridge allows transfer of a fluid when the container is in a predetermined orientation. This is disclosed in figure 4b. Claim 32 was amended to recite that the holder is effective to orient the container in the predetermined orientation. The frame 32 is a specific disclosure of a holder, and figure 3b shows the holder orienting the container in the predetermined orientation. Claim 32 was amended to add

the step of adding a physiological product to one of the chambers. This is disclosed at column 2, beginning at line 50. Claim 32 was also amended for grammatical reasons (e.g., plural to singular) or to change "position" to "orient." These changes are mainly stylistic and are clearly supported by the disclosure.

Claims 33 and 36 were amended to delete the word "removable." A lid is disclosed as element 11, and there was no requirement that it be removable or not.

Claim 35 was amended for clarity to recite the top portions of the first and second chambers, respectively, as the first top portion and the second top portion. Claim 35 was amended to add the recitation of a means for maintaining sterility. This is language permitted by 35 USC 112, sixth paragraph, and reads on the ports 13 and 15 and their equivalents.

Claims 38 and 43 were amended to add the step of placing the physiological product in one of the chambers. This is clearly supported by the specification at column 2, beginning at line 50.

Claim 39 and 42 were amended for grammatical purposes to change a "centrifuge rotor" to a "rotor of said centrifuge."

Claim 47 was amended to change "container" to "method" to conform to the parent claim.

Claim 48 was added, but this has now been canceled.

Amendments to claim 42 on May 14, 2003

Claim 42 was amended to remove the limitation that the locking plate must engage the frame. While this is the preferred embodiment, it is submitted that the original disclosure would have disclosed the generic recitation to one of ordinary skill in the art.

Amendments to claim 38 on July 3, 2003

Claim 38 was amended to recite "sterile access" instead of access "to maintain sterility." This is stylistic and is fully supported by the disclosure at column 4, lines 4-5.

Rejections

The interview with Examiner Cooley on August 19, 2003, is noted. At the interview the references to McFarland, Raccuglia, Crippa and Onishi were discussed. Reconsideration of the rejections is again requested.

Claims 35 and 43 now clearly distinguish over Raccuglia, McFarland, Onishi and Crippa in the recitation of chambers with adjacent top portions and means for providing sterile transfer near the tops of at least one of the chambers. Raccuglia does not have adjacent chambers, and McFarland, Onishi and Crippa do not provide sterile access to the chambers by structure located at the upper parts of the chambers.

Accordingly, it is submitted that this application is in condition for allowance, and an early indication thereof is respectfully requested. The examiner is invited to contact the undersigned if any matter remains outstanding.

All necessary extensions of time are requested. Please charge any necessary fees and credit any excess to deposit account 50-1088.

Respectfully Submitted,
CLARK & BRODY

A handwritten signature in cursive script, appearing to read "Conrad Clark".

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October 7, 2003

MARKED UP CLAIMS

09/838,300

October 7, 2003

35. (Twice Amended) In a method of treating physiological fluids, the improvement comprising providing a container adapted to contain said fluids during treatment, wherein said container comprises:

[at least] a first **sterile** chamber having a first top portion, a first bottom portion and a first set of walls;

a second **sterile** chamber **adjacent said first sterile chamber and** having a second top portion **adjacent said first top portion**, a second bottom portion and a second set of walls;

a bridge connecting said first top portion of the first chamber and said second top portion of the second chamber, such that a fluid can be transferred from the first chamber to the second chamber while the container is positioned at a predetermined angle, and means for **sterile transfer of a fluid to or from at least one of said chambers independently of the other of said chambers and located near the top of at least one of said chambers** [maintaining sterility of said first and second chambers during addition or removal of fluids to said chambers], and

placing a physiological fluid in one of said chambers.

38. (Thrice Amended) A method for treating physiological products and maintaining sterility of said products during said treating comprising:

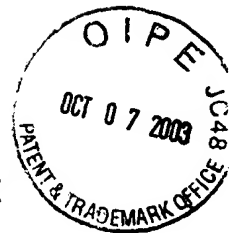
providing a container having a plurality of closed, sterile fluid-receiving chambers, a bridge forming a fluid path allowing

fluid communication between a first of said chambers and a second of said chambers when said container is in a predetermined orientation, and at least one access port allowing sterile access to at least one of said chambers, providing a centrifuge having a holder removably receiving said container and allowing said container to assume a first orientation wherein a physiological product in one of said chambers is subjected to centrifugation and said predetermined orientation wherein fluid in said first of said chambers flows along said fluid path to said second of said chambers, and **said centrifuge comprises a locking element that selectively holds said container in said predetermined orientation, and** placing a physiological product in one of said chambers.

40. (Amended) A method according to claim 38 wherein said [centrifuge further] **locking element** comprises a movable locking plate that is movable between free and locking positions, wherein said **movable locking** plate allows said container to assume said first orientation when in said free position and holds said container in said predetermined position when in said locking position.

42. (Thrice Amended) A method according to claim 38 wherein said holder comprises a frame pivotally mounted to a rotor of said centrifuge, and said [centrifuge further] **locking element** comprises a movable locking plate that is movable between free and locking positions, wherein said **movable locking** plate allows said container to assume said first orientation when in said free position and holds said container in said predetermined position when in said locking position.

43. (Twice Amended) In a method of treating physiological fluids, the improvement comprising providing a container adapted to contain said fluids during treatment, wherein said container comprises a base forming a plurality of sterile chambers, each of said chambers having a bottom and a top, a bridge connecting **top portions of at least two of said chambers** and arranged to provide a sterile fluid channel from a first of said at least two sterile chambers to a second of said at least two sterile chambers when said container is in a predetermined orientation, a lid closing said top of each of said plurality of chambers, and **an access port near the top of at least one of said chambers that allows sterile transfer of a liquid to or from said at least one of said chambers independently of the other of said chambers** [access ports that provide access to the chambers while maintaining sterility], and placing a physiological fluid in one of said plurality of sterile chambers.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

WELLS, et al.

Serial No.: 09/838,300

Art Unit: 1723

Reissue of U.S. Patent No. 5,895,346

Filed: April 20, 2001

For: AUTOMATIC MULTIPLE DECANTING CENTRIFUGE

REISSUE DECLARATION AND POWER OF ATTORNEY

The undersigned applicants hereby declare as follows:

1. We believe the original patent to be partly inoperative or invalid by reason of our claiming less than we had the right to claim in the patent.
2. An error in the original patent was the failure to claim overlooked embodiments that provide treatment of physiological fluids in a centrifuge in such a manner that sterility of the fluids is maintained during treatment.
3. All errors that are being corrected in the present reissue application up to the time of filing this declaration arose without any deceptive intention on our part.
4. We have reviewed and understand the contents of the specification, including the claims.
5. We believe ourselves to be the original, first, and joint inventors of the subject matter claimed and for which a patent is sought.
6. We acknowledge the duty to disclose to the Office all information known to us to be material to patentability as defined in 37 CFR §1.56.
7. All statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001 and that such willful false statements may

jeopardize the validity of the application, and patent issued thereon, or any patent to which this declaration is directed.

8. We hereby appoint Conrad J. Clark (Reg. No. 30,340) and Christopher W. Brody (Reg. No. 33,613) as our attorneys to prosecute this application, with full powers of substitution. Please send all correspondence to:

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John R. Wells

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Date: June __, 2003

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Date: June 17, 2003



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WELLS, et al.

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4. We have reviewed and understand the contents of the specification, including the claims.
5. We believe ourselves to be the original, first, and joint inventors of the subject matter claimed and for which a patent is sought.
6. We acknowledge the duty to disclose to the Office all information known to us to be material to patentability as defined in 37 CFR §1.56.
7. All statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001 and that such willful false statements may

jeopardize the validity of the application, and patent issued thereon, or any patent to which this declaration is directed.

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